**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

| | |
|---|---|
| KAREN ROBERTSON and SAMUEL ROBERTSON,<br><br>Plaintiffs,<br><br>vs.<br><br>JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CO., AND MITSUBISHI TANABE PHARMA CORP.,<br><br>Defendants. | CIVIL ACTION NO.: 3:16-cv-02050-BRM-LHG<br><br>CIVIL ACTION<br><br>(Document Filed Electronically)<br><br>**Return Date: September 6, 2016** |

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS JANSSEN PHARMACEUTICALS, INC. AND JOHNSON & JOHNSON'S MOTION TO DISMISS**

Christopher A. Seeger
Jeffrey Grand (*pro hac vice* pending)
Daniel R. Leathers
**Seeger Weiss LLP**
550 Broad Street Suite 920
Newark, New Jersey 07102
Telephone: (973) 639-9100
Facsimile: (973) 639-9393
E-mail: cseeger@seegerweiss.com
E-mail: jgrand@seegerweiss.com
E-mail: dleathers@seegerweiss.com

*Attorneys for Plaintiffs*

# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

## Federal Cases

**State Cases**

**State Statutes**



**Federal Rules**



**Federal Regulations**



**Other Authorities**

## I. INTRODUCTION

Invokana is a name-brand medication prescribed for the treatment of Type 2 diabetes. Plaintiff Karen Robertson developed diabetic ketoacidosis and kidney damage due to ingestion of Invokana. As a result, she asserts 13 claims against Janssen Pharmaceuticals, Inc. ("Janssen"), Johnson & Johnson ("J&J"), and Mitsubishi Tanabe Pharma Corporation ("Mitsubishi")" Her husband asserts derivative loss of consortium claims. Janssen and J&J ("Defendants") have moved to dismiss Plaintiffs' complaint. The Court should deny Defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). The Court should deny Defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

***First***, Defendants put the Rule 8 plausibility standard on a pedestal equal to that of a claim sounding in fraud under 9(b). As a result of that unfounded supposition, together with a circumscribed reading of Plaintiffs' complaint, Defendants cobble together case law to seek dismissal, citing to numerous (off-point) medical *device* cases or *generic* pharmaceutical cases in defense of this *brand-name* pharmaceutical drug suit. As medical devices and generic drugs are subject to different rules than brand-named prescription medications, the cases cited by Defendants are inapplicable here. Applying the correct Rule 8 plausibility standard with on-point case law nets an entirely different result: her claims survive under both New Jersey and Tennessee law.[1] Mrs. Robertson is entitled to punitive damages under either New Jersey or Tennessee law.

***Second***, Mrs. Robertsons' design defect-based claims (Counts 2 and 5–7) are not preempted by federal law. Defendants again cherry-pick from limited case law supporting their sweeping contention that all design defect cases against generic **and brand-name** prescription

[1] This court need not, at this juncture reach a choice of law analysis because Plaintiffs' claims survive under both states' laws. To the extent that the Court may ultimately believe that any of Plaintiffs' claims fail under either states' laws, that is a question for another day. *See* Section III, *infra*.

drug manufacturers would be preempted despite binding Supreme Court precedent to the contrary.

***Third***, Defendants assert that claims against Johnson & Johnson are preempted because Johnson & Johnson is merely a "holding company" and had no authority to amend the design or labeling for Invokana. This is inaccurate. As demonstrated by judicially-notable materials publicly available from both the FDA and Johnson & Johnson's own website, J&J actively manages Janssen Pharmaceuticals and even shares research and marketing personnel with Janssen. It was and remains intimately involved in the development and labeling of Invokana. Thus, Plaintiffs' claims against Johnson & Johnson are not preempted.

## II. BACKGROUND

Mrs. Robertson began using Invokana to treat her diabetes in 2015 and subsequently experienced kidney damage and diabetic ketoacidosis. *See* Compl. ¶¶ 4, 8, 28, 33, 41-42. Plaintiffs allege that Defendants failed to adequately warn of the risk of kidney damage from ingesting Invokana, along with other injuries that can be caused by the drug, some of which may also result in kidney damage.

But Plaintiffs allege more than the mere use of Invokana in connection with Mrs. Robertsons' injuries. Plaintiffs allege that Defendants knew the mechanism of action of the sodium-glucose cotransporter 2 inhibitors and that Invokana's mechanism of action results in severe kidney damage, as well as other injuries. *Id*. ¶¶ 18-22. Moreover, Defendants were aware of a growing number of Invokana adverse event reports yet did not change the label, or otherwise warn physicians, patients, or the public at large of those dangers. *Id.* ¶¶ 23-28, 34-37, 39.

## III. CHOICE OF LAW

On a motion to dismiss for failure to state a claim, a "defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). In order for Defendants to successfully dispose of ***any*** of Plaintiffs' claims, Defendants bear the

burden on showing that her claims fail under **both** Tennessee and New Jersey law in their opening brief. Stated another way, because Defendants have failed to make any claim-by-claim arguments required for a choice-of-law analysis – let alone any discussion of conflict at the outset – Defendants bear the burden of proving the claims fail under **both** of the set-forth states (Tennessee and New Jersey) for each claim.

In any event, choice of law issues are inappropriate to resolve on a motion to dismiss in the first instance when key factual matters have yet to develop. *See, e.g., Argabright v. Rheem Mfg. Co.*, No. 15-5243, 2016 WL 3536621, at *4 (D.N.J. June 28, 2016) (denying a motion to dismiss and simultaneously finding that "the factual record is not full enough to make a choice of law determination, the Court will postpone the choice of law analysis to a later stage"); *Krys v. Aaron*, 106 F. Supp. 3d 472, 481 (D.N.J. 2015) (stating that "the factual inquiry necessary for a choice of law analysis often proves 'inappropriate or impossible' at the motion to dismiss stage 'when little or no discovery has taken place.'") (quoting *Erlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 700-01 (D.N.J. 2011) (citation omitted) (also citing additional cases that have determined that a choice-of-law analysis is premature at the motion to dismiss stage); *Snyder v. Farnam Co.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011) (same); *Harper v. LG Elecs. USA, Inc.*, 595 F. Supp. 2d 486, 491 (D.N.J. 2009) (same).

## IV. LEGAL STANDARD

A plaintiff's pleading requires "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570, 127 S. Ct. 1955). To meet the plausibility standard, a plaintiff's allegations must show that defendant's liability is more than "a sheer possibility." *Id.* "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at

678 (quoting *Twombly*, 127 S. Ct. at 1955).

"The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* All a Plaintiff must show are facts that tend to "'raise a right to relief above the speculative level[.]'" *Siwulec v. J.M. Adjustment Servs., LLC*, 465 F. App'x 200, 202 (3d Cir. 2012) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "The issue before the Court is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence in support of the claims." *Touristic Enters. Co. v. Trane, Inc.*, Civ. Act. No. 09-02732, 2009 WL 3818087, at *1 (D.N.J. Nov. 13, 2009) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)); *see also Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (relying on *Twombly* to hold that to survive a motion to dismiss a complaint must assert "enough facts to raise a reasonable expectation [] discovery will reveal evidence of the necessary element").

The Third Circuit observed, applying *Twombly* and *Iqbal*, that in evaluating the legal sufficiency of a complaint's allegations, a court "accept[s] all factual allegations as true, construe[s] the complaint in the light most favorable to the plaintiff, and determine[s] whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips*, 515 F.3d at 233 (quoting *Pinker v. Roche Holdings Ltd.*, 292 F.3d 361, 374 n.7 (3d Cir. 2002)). "The Court's role is not to determine whether the non-moving party 'will ultimately prevail' but whether that party is 'entitled to offer evidence to support the claims.'" *Williams v. Hospice*, No. CV-16-2095, 2016 WL 4149987, at *3 (D.N.J. Aug. 3, 2016) (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011)).

The Court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64. Moreover, "[i]n deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint,

matters of the public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (emphasis added).

Additionally, F.R.C.P. Rule 15(a) declares that leave to amend "shall be freely given when justice so requires." "[I]f a complaint is subject to a Rule 12(b)(6) dismissal, a district court must permit a curative amendment unless such an amendment would be inequitable or futile." *Phillips*, 515 F.3d at 245 (citing *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004)).

As developed below, the Complaint states allegations that give rise to a plausible, not merely possible, entitlement to relief. Plaintiffs' allegations are not threadbare recitals of the elements of a cause of action but instead, provide more than sufficient detail for the Defendants to have notice of the claims against them.

## V. ARGUMENT

### A. Mrs. Robertson's Claims are Sufficiently Pled under Both Tennessee and New Jersey Law

#### 1. Plaintiffs Specify the Extent and Roles of Each Defendant's Wrongdoing

Janssen, as a wholly owned subsidiary of J&J, "marketed, advertised, distributed, and sold" Invokana in addition to "researching, developing, designing, licensing, manufacturing, [and] supplying" it. Compl. ¶¶ 9, 15. J&J too was directly involved in such "researching, developing, designing, licensing, manufacturing, distributing, supplying, selling[,] marketing, and introducing [of Invokana] into interstate commerce." *Id.* ¶ 10.

Defendants, however, aver to this Court that J&J is a mere "holding company and did not design, manufacture or sell Invokana." Def. Mot. at 5. Defendants artfully avoid Plaintiffs' other allegations (which this Court must accept as true) – that J&J also partook in the "researching … developing, and introducing [of Invokana] into interstate commerce." Compl. ¶ 10. Defendants

do not dispute these roles, nor can they.

Defendants emphasize the fact that Janssen is the company that manufactures Invokana in Puerto Rico. Publicly-available documents, judicially noticeable by this Court,[2] accessed from FDA and on J&J's own website, verifies J&J's involvement in the labeling, product launch, and marketing of Invokana. Thus, even absent further discovery, based on the following, there is no question that J&J was involved in the product alleged to cause Mrs. Robertson's injuries.

J&J posted an online article entitled "Behind the Product Labels."[3] The article details how a third-party label manufacturer is **"**a true partner ***for Johnson & Johnson"*** because the label manufacturer produced Invokana bottle labels in anticipation of FDA approval yet stood at the ready over the Easter holiday to change the label – at ***J&J's*** direction – in the event of "a potential request from the FDA for changes to the label." *Id.* J&J's Director of Trade Accounts is quoted

---

[2] For the same reasons that Defendants cite that this Court make take judicial notice of FDA documents, this court may do the same of the FDA documents cited herein. *See* Def. Mot. at 5 n.6; *see also Horne v. Novartis Pharms. Corp*., 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008) ("The Court may take judicial notice of and consider the public record of the FDA . . . .").

Similarly, the Defendants' own website may be judicially noticed. *See O'Toole v. Northrop Grumman Corp*., 499 F.3d 1218 (10th Cir. 2007) (holding that the district court had abused its discretion in refusing to take judicial notice of information from the defendant's website under Rule 201); *see also Hendrickson v. eBay, Inc*., 165 F. Supp. 2d 1082, 1084 (C.D. Cal. 2001) (same); *Under a Foot Plant, Co. v. Exterior Design, Inc.,* No. 6:14-cv-01371, 2015 2015 WL 1401697, at *2 (D. Or. Mar. 24, 2015) (taking judicial notice of an archived version of the defendant's website).

The Court may accept the facts contained on Defendants' own website for the truth of the matter asserted therein. "For purposes of a 12(b)(6) motion to dismiss, a court may take judicial notice of information publicly announced on a party's website, as long as the website's authenticity is not in dispute and 'it is capable of accurate and ready determination.'" *Doron Precision Sys., Inc. v. FAAC, Inc*., 423 F. Supp. 2d 173, 179 n.8 (S.D.N.Y. 2006); *accord Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 167 (S.D.N.Y. 2015) (taking judicial notice of printouts of the defendant's own website because defendant did "not actually dispute the factual material reflected in [them]," but rather "simply . . . prefer[red] that the Court not consider [them]").

[3] Exhibit A, Behind the Product Labels, *available at* https://www.jnj.com/sites/default/files/pdf/JJ%20Diversity%20--%20National%20Label%20and%20Cardinal%20--%2012-23-14.pdf .

as the person "who manages the relationship between [the third-party label manufacturer] **and Johnson and Johnson** and [who] over saw the product [Invokana's] launch."[4]

J&J's own website also posted (and continues to host) a "Media Fact Sheet" about Invokana, detailing in more generic terms understandable to the public at large about the drug's mechanism of action.[5] Moreover, even though J&J attempts to establish itself as a mere holding company through its financial filings (*see* Def. Mot. at n. 5), other financial filings on J&J's own website further point to the importance of Invokana to J&J's bottom line. For example, J&J's 2012 Annual report exclaimed that "**We [J&J]** have an exciting and late-stage pipeline of differentiated medicines. New Drug Applications are presently under review in the United States and in the European Union seeking approval for INVOKANA (canagliflozin), **our [J&J's]** first pharmaceutical treatment for patients with type 2 diabetes."[6] Thus, to the extent J&J attempts to shield itself from liability, by creating a set of nested Russian dolls, J&J is nevertheless at the top of the stack and directly involved, understandably, in the affairs of its underlings.[7] To wit, J&J's 2015 Annual Report states that:

> The **Executive Committee of Johnson & Johnson is the principal management group** responsible for the strategic operations and allocation of the resources of the Company. This Committee **oversees and coordinates the activities of the Company's three business segments**: Consumer, **Pharmaceutical** and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international

[4] *Id* (emphasis added).

[5] Exhibit B, Media Fact Sheet, *available at* https://www.jnj.com/sites/default/files/pdf/Janssen_INVOKANA%20FactSheet.pdf.

[6] Exhibit C, J&J's 2012 Annual Report at 7, *available at* https://www.jnj.com/sites/default/files/pdf/JNJ2012annualreport.pdf (emphasis added).

[7] Exhibit D, *see* 2015 First Quarter Report of Drug Quarter-over-Quarter sales, *available at* http://www.jnj.com/sites/default/files/pdf/Johnson-Johnson-First-Quarter-2015-Financial-Charts.pdf (listing Invokana).

> operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies.[8]

J&J describes Invokana as one of the products in its Pharmaceutical segment in its 2015 Annual Report.[9] Indeed, J&J was involved with Invokana from its initial NDA application. Administrative documents & correspondence for the drug approval package for Invokana establishes J&J's role in the submission of Invokana for the FDA's approval.[10] As part of the NDA application, all FDA investigators had to reveal any financial conflicts of interest. For Invokana, a minimum of thirteen FDA investigators received (and were forced to disclose) various consulting fees ***from J&J*** (not Janssen).[11]

Moreover, Brandon Porter is listed as the Associate Director, Regulatory Affairs, for Janssen Research & Development on the NDA-related correspondence. Brandon Porter, however, wears two hats. He was simultaneously (and remains to be) the Associate Director of Global Regulatory Affairs *for J&J* and, while at J&J, was a "[m]ember of the canagliflozin regulatory team that gained FDA approval of Invokana."[12] Similarly, Leslie Schaefer, a consumer brand director at *J&J*, is the director of marketing for Invokana.[13]

---

[8] Exhibit E, J&J 2015 Annual Report, *available at* http://files.shareholder.com/downloads/JNJ/1709744668x0x881109/474857DD-8E67-43B1-BB38-0A9712D93545/2015_annual_report_.pdf, at 1 (emphasis added).

[9] *Id.* at 2.

[10] All FDA drug approval package documents are *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000TOC.cfm.

[11] Exhibit F, FDA Medical Reviews at 23, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000MedR.pdf.

[12] Exhibit G, FDA Administrative Documents & Correspondence at 88, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000Admincorres.pdf; *see also* Exhibit H, LinkedIn, Brandon Porter, *available at* https://www.linkedin.com/in/brandon-porter-3aa46a.

In sum, Janssen and J&J are not haphazardly 'lumped together.' Johnson & Johnson has a special role on the development and marketing of Invokana in its supervision of Janssen's business.[14] *See BK Trucking Co. v. PACCAR, Inc.*, No. 15-2282, 2016 WL 3566723, at *19 (D.N.J. June 30, 2016) (naming defendants together in one action was allowed because "Plaintiffs have alleged that all defects requiring repair [when the specific] component systems is uniquely within Defendants' control. The Court cannot expect Plaintiffs to provide more specificity about the [component] without the benefit of discovery.").

**2. Mrs. Robertsons' claims are plausibly pled under Tennessee law**

"[U]nder Tennessee law, establishing a prima facie products-liability claim requires that "the plaintiff must show: (1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product." *Sigler v. American Honda Motor Co.*, 532 F.3d 469, 483 (6th Cir. 2008).

According to T.C.A. § 29–28–105(a), "[a] manufacturer or seller of a product shall not be liable for any injury to person or property caused by the product unless the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." A defective condition is defined as "a condition of a product that renders

[13] Exhibit I, LinkedIn, Leslie Schaefer, *available at* https://www.linkedin.com/in/leslieschaefer66bb744.

[14] For example, many of the top leadership of J&J wear two hats and sit on leadership team of Janssen as well. As a few examples, Joaquin Duato is the Executive Vice President and Worldwide Chairman, Pharmaceuticals for Johnson & Johnson, but also is listed as part of Janssen's leadership. *See* "Our Leadership, Janssen", *available at* http://www.janssen.com/about/our-leadership. The same is true for Paul Stoffels, Chief Scientific Officer, Johnson & Johnson and Worldwide Chairman, Pharmaceuticals; Dr. William Hait, Global Head, Research & Development; Patrick Verheyen, Global Head of Business Development; and Linda Fedow, Global Lead, Pharmaceuticals Communication & Public Affairs. *Id.*

it unsafe for normal or anticipatable handling and consumption." T.C.A. § 29–28–102(2). A product is unreasonably dangerous when "a product is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics, or that the product because of its dangerous condition would not be put on the market by a reasonably prudent manufacturer or seller assuming that he knew of its dangerous condition." T.C.A. § 29–28–102(8).

Mrs. Robertson has satisfied these preliminary elements for every form of her product liability claims (manufacturing defect, failure to warn, and design defect). *First*, she was injured. Compl. ¶ 4 ("After beginning treatment with INVOKANA … Plaintiff KAREN ROBERTSON developed kidney damage and diabetic ketoacidosis."). *Second*, Plaintiff pled that Invokana is unreasonably dangerous. *See* Compl. ¶¶ 19-24 (explaining the increased dangers of SGLT2 diabetes drugs over non-SGLT2 drugs—including and especially Invokana—in light of mounting FDA adverse event reports). *Third*, the Invokana prescribed and consumed by Mrs. Robertson was in the same condition in which it was sold, and was unaltered. Compl. ¶ 29.

**a. Manufacturing Defect (Count 1)**

Under Tennessee law, establishing a prima facie products liability claim requires that the plaintiff must show:

> (1) the product was defective and/or unreasonably dangerous, (2) the defect existed at the time the product left the manufacturer's control, and (3) the plaintiff's injury was proximately caused by the defective product.

*Fleming v. Janssen Pharms., Inc.*, No. 2:15-cv-02799, 2016 WL 3180299 (W.D. Tenn. June 6, 2016).

"Tennessee products liability law … recognizes two different tests for determining whether a product is unreasonably dangerous. The first, the consumer-expectation test, is used where a product is "dangerous to an extent beyond that which would be contemplated by the ordinary

consumer who purchases it." *Ray ex rel. Holman v. BIC Corp.*, 925 S.W.2d 527, 530 (Tenn. 1996); *see also Brown v. Raymond Corp.*, 432 F.3d 640, 643-44 (6th Cir. 2005). The second, the prudent-manufacturer test, imputes knowledge of the dangerous condition to the manufacturer, and then asks "whether, given that knowledge, a prudent manufacturer would market the product." *Ray*, 925 S.W.2d at 530. As the Tennessee Supreme Court has articulated, "[t]he consumer expectation test is, by definition, buyer oriented; the prudent manufacturer test, seller oriented." *Id.* at 531; *Johnson v. Manitowac Boom Trucks, Inc.*, 484 F.3d 426, 428-29 (6th Cir. 2007).

Specifically, Mrs. Robertson alleges that the Invokana she consumed deviated from the "performance standards" that J&J and Janssen both set for "otherwise identical units [of Invokana pills] manufactured to the same manufacturing specifications or formulae." Compl. ¶ 46; *see also id.* ¶ 45; *Kelley v. Howard Berger Co.*, No. 13-96, 2013 WL 4014748, at *3 (E.D. Tenn. Aug. 6, 2013) (claim sufficiently pled where Plaintiff "identifies a specific product defect."). Her complaint satisfies both defect tests. Given the allegations in her complaint regarding adverse events received by the Defendants, the complaint illustrates that Defendants did not act as prudent manufacturers. Her allegations regarding her injury, and the lack of warning she received from her physician, show that her expectations regarding the product were clearly not met.

Defendants confuse the Rule 9 heightened particularity pleading standard applicable to fraud-based claims for Rule 8-based claims, like this one (subject to "plausibility"). Plaintiffs need not show, at this stage, "how" J&J and Janssen's manufacturing defect caused her injuries and "how" the Invokana pills consumed by Mrs. Robertson were different than its intended design. Def Mot. at 7. To require such facts at this stage would be akin to requiring an expert report filed with the complaint. This is not the law. *See, e.g., Richardson v. GlaxoSmithKline*, 412 F. Supp. 2d 863, 868 (W.D. Tenn. 2006) (internal citation omitted) ("[U]nder Tennessee law, expert testimony is required to establish liability in cases alleging manufacturing and design defects.").

Defendants contend that "Courts in two other Invokana cases have dismissed virtually identical manufacturing defect claims as insufficiently pled."[15] Def. Mot. at 8. Neither of these cases are Tennessee cases, and Defendant provides no further discussion of the manufacturing allegations in those complaints.

**b. Design Defect (Count 2)**

In order to establish a defective design claim, the plaintiff must "trace the injury to some specific error in construction or design of the [product]." *Browder v. Pettigrew*, 541 S.W.2d 402, 404 (Tenn. 1976). Tennessee Code Annotated § 29-28-102(2) (1980) defines defective condition as "a condition of a product that renders it unsafe for normal or anticipatable handling and consumption." Consideration should be given "to the customary designs, methods, standards and techniques of manufacturing, inspecting and testing by other manufacturers or sellers of similar products."

In weighing the risk-utility benefit of Invokana, a reasonable jury may find, as Plaintiffs have pled, that Invokana is "more dangerous" and poses more "risks [when compared to] other [alternative] medications and similar drugs on the market to treat type 2 diabetes." Compl. ¶ 51(b). *Kelley v. Howard Berger Co*., No. 13-96, 2013 WL 4014748, at *3 (E.D. Tenn. Aug. 6, 2013) (claim sufficiently pled where Plaintiff "identifies a specific product defect.").

Plaintiff's design defect claim satisfies the Rule 12(b)(6) standard, because she alleges each element of a design defect claim. Although Defendant argues to the contrary, Plaintiff alleges a defect in the design of Invokana, that is, that the drug caused her permanent physical injuries of diabetic ketoacidosis and kidney damage, Compl. § 51. Plaintiff further alleges that the defect proximately caused the harm for which recovery is sought. Compl. § 41. Finally, Plaintiff alleges

[15] *Guidry v. Janssen Pharms., Inc*., 2016 WL 633673 (E.D. La. Feb. 17, 2016) and *Brazil v. Janssen Research & Dev. LLC*, No. 4:15-cv-0204 (N.D. Ga. Mar. 24, 2016).

that a feasible design alternative existed that would have to a reasonable probability prevented the harm. Compl. § 52. Because Plaintiff has satisfactorily alleged a design defect claim under Tennessee law, Defendant's motion to dismiss should be denied on this ground.

Again, Defendants confuse the Rule 9 heightened particularity pleading standard applicable to fraud-based claims for Rule 8-based claims. Plaintiffs need not support their complaint with expert testimony as to complicated matters – matters reserved for an expert, at this stage of the litigation. According to Defendants, Plaintiffs must present – in their complaint – an expert report on how SGLT2 inhibitors, and Invokana specifically, increase the risk of kidney damage. It is unclear how such a presentation would be done absent an expert report. So long as the litigation proceeds and Plaintiffs' expert's theory is viable, it is the trier of fact who is to decide whether J&J and Janssen's design was reasonable under a risk-utility balancing test. Plaintiffs need to prove their case in the complaint.

Defendants' citations to *Fleming v. Janssen Pharmaceuticals*, No. 2:15-cv-02799, 2016 WL 3180299 (W.D. Tenn. May 6, 2016), *Guidry* and *Brazil* do not warrant dismissal of this claim. These were different complaints, filed by different plaintiffs, and deficiencies that the courts found in them are not present in Mrs. Robertson's complaint.

**c. Failure-to-Warn (Count 3)**

"Tennessee courts have long held that a manufacturer may be held strictly liable for failing to warn consumers of the dangers of a particular product at the time of sale." *Flax v. DaimlerChrysler Corp.*, 272 S.W.3d 521, 541 (Tenn. 2008). A warning is inadequate if it does not contain a full and complete disclosure of the potential adverse reactions. *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994). Criteria to consider are adequacy of indications of the scope of danger, the extent or seriousness of harm that could result from misuse, and the consequences of failing to follow the warning. *Id.* Also, the warning must be conveyed through

adequate means with physical aspects that would alert a reasonably prudent person to the danger. *Id.*

Plaintiffs' failure to warn claim is simple: Mrs. Robertson suffered kidney damage and diabetic ketoacidosis and Defendants failed to adequately warn about such risks. Compl. ¶ 4; ¶ 54. There is no disconnect between the failure to warn claim and the injuries Mrs. Robertson suffered as Defendants contend. Def. Mot. at 10.

Notably, Defendants fail to acknowledge that in May of this year, the FDA required Defendants to *strengthen* the warnings for Invokana. Specifically, the FDA requested new precautions under two of the six safety labeling sections for Invokana.[16] Among those changes was an added section under "WARNINGS AND PRECAUTIONS" for "Acute Kidney Injury and Impairment in Renal Function," including "**postmarketing reports** of acute kidney injury, some requiring hospitalization and dialysis, in patients receiving INVOKANA".[17] The same revised warnings included the fact that doctors should "consider factors that may predispose patients to acute kidney injury including hypovolemia, chronic renal insufficiency, congestive heart failure and concomitant medications." *Id.*

Another critical change to the label was an added section under "WARNINGS AND PRECAUTIONS" for "Ketoacidosis," including "Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization have been identified in postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose co-

[16] *See* Exhibit K, FDA May 2016, Drug Safety Labeling Changes, *available at* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm505586.htm.

[17] *See* Exhibit L, FDA Invokana warning changes over Time, *available at* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm400577.htm (emphasis added).

transporter-2 (SGLT2) inhibitors, including INVOKANA."[18] The same revised warnings included the fact that "in many of the postmarketing reports … the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed…." Doctors are now instructed that [b]efore initiating INVOKANA, they should "consider factors in the patient history that may predispose to ketoacidosis." *Id.* Further, in June of this year, the FDA released an over-arching "Safety Announcement" applicable to Invokana.[19] This information, and these warnings, were not available to Plaintiff's physician before Invokana was prescribed.[20] It therefore makes no sense for Defendants to claim that Plaintiffs' failure to warn claim is not plausible when the current label, although not the one in effect when she used the product, contains a warning for the very injury she suffered.

Defendants' argument ignores the Rule 8 plausibility standard and points out alleged gaps in Plaintiff's allegations, *see* Def. Mot. at 12-13. On a motion to dismiss, the Court must accept these facts as true. *Kelley v. Howard Berger Co.*, No. 13-96, 2013 WL 4014748, at *1 (E.D. Tenn. Aug. 6, 2013). Defendants further attack the use of adverse event reports, *see* Def. Mot. at 13, and state that "such reports do not and cannot establish causation." Of course, at this stage of the litigation, Plaintiff "does not need detailed factual allegations," *id*. at 2 (quoting *Twombly*, 550

[18] *See* Exhibit L, FDA Invokana warning changes over Time, *available at* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm400577.htm (emphasis added).

[19] *See* Exhibit M, Invokana Safety Announcement, *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/UCM506772.pdf and Exhibit N http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm506554.htm (similar).

[20] *Compare* Exhibit J, 2013 Invokana warnings, *available at* http://www.accessdata.fda.gov/drugsatfda_dsssocs/label/2013/204042s000lbl.pdf (*e.g.*, no diabetic ketoacidosis warning) *to* Exhibit O, Revised May 2016 Invokana Warnings, *available at:* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s011lbl.pdf (diabetic ketoacidosis warning added).

U.S. at 555). Further, Plaintiff has no requirement to establish causation – such evidence will be provided by experts. *See, e.g., Richardson v. GlaxoSmithKline*, 412 F. Supp. 2d 863, 868 (W.D. Tenn. 2006) ("[U]nder Tennessee law, expert testimony is required to establish liability in cases alleging manufacturing and design defects.") (internal citations omitted).

Defendants' citation to *Fleming v. Janssen Pharmaceuticals*, No. 2:15-cv-02799, 2016 WL 3180299 (W.D. Tenn. May 6, 2016) is unavailing. In *Fleming*, the court specifically found that Plaintiffs' allegations "made only conclusory statements as to the failure of Defendants to warn about the dangers of Invokana. *Id*. at *7. That is not the case here.

Defendants' make the specious argument that a statement in the 2013-version of the Invokana label that "[r]enal function abnormalities [that] can occur" serves as an adequate warning for the kidney damage suffered by Mrs. Robertson. While Plaintiffs believe this argument stretches the limits of the imagination, the adequacy of this purported warning should be a factual determination by the jury.[21]

The warnings in effect at the time of Mrs. Robertson's consumption in 2015 instead contained cryptic warnings about creatinine and"[r]enal function abnormalities [that] can occur" pale in comparison to known "Acute Kidney Injury and Impairment" occurring in "postmarketing reports" that required "hospitalization and dialysis." Similarly, the recommendation for routine kidney screening appears nowhere in the version of the warnings in effect at the time of Mrs. Robertson's consumption.[22] In any event, the fact that Defendants' only serious support for the

[21] The 2013 warnings were effect at the time of Mrs. Robertson's consumption and did not change in the year 2015. *See id.*

[22] *Compare* Exhibit J, 2013 Invokana warnings, *available at* http://www.accessdata.fda.gov/drugsatfda_dsssocs/label/2013/204042s000lbl.pdf *to* Exhibit O, Revised May 2016 Invokana Warnings, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s011lbl.pdf.

dismissal of Plaintiffs' failure-to-warn claim is to quibble about the strength (or lack thereof) of the 2013-version (in effect in 2015) of the warnings versus the present warnings speaks volumes. These are questions of fact for a jury, not to be resolved as a matter of law on a motion to dismiss.

Further, Defendants' 2013 label, attached as Exhibit J, omits material safety information about Invokana. "Fraud by omission ... is by its very nature, difficult to plead with particularity." *Dineen v. Pella Corp.*, 2015 WL 6688040, at *10 (D.S.C. Oct. 30, 2015).

| | |
|---|---|
| **Who:** | Janssen and J&J. |
| **What:** | Defendants "omitted important information about the safety and quality of INVOKANA in the documents and marketing materials Defendants provided to physicians and the general public." Compl. ¶ 138(b). Namely, nowhere in the 2013 label do the Defendants disclose the risks of diabetic ketoacidosis. It was not until the 2016 label that Defendants disclosed any such risk. Exhibit O. Further, nowhere in the 2013 label do the Defendants disclose the risks of kidney damage to the same extent as the 2016 label, which, among other things, reported "Acute Kidney Injury and Impairment" that required "hospitalization and dialysis." |
| **When:** | March 2013 (date on page 41 of Ex. J). |
| **Where:** | In product boxes, disseminated to treating doctors and to the public at large. |
| **How:** | By misleading prescribing doctors and the public at large as to the relative safety of Invokana when compared to other similar diabetic medications. *See also* Compl. ¶¶ 116, 120-123, 137, 150. |
| **Why:** | "[S]ales and profits at the expense of the health and safety of the public." Compl. ¶ 173. |

**3. There is No Basis for Striking any of Plaintiffs' New Jersey Claims**

**a. It is too early to determine if Plaintiffs' implied warranty, negligence-based, and fraud-based claims (Counts 5–11) are subsumed by the New Jersey Product Liability Act**

Although the Court may determine that certain claims are subsumed by the NJPLA at a later time, it is premature to make this determination at this phase absent a choice of law analysis. Defendants have made no meaningful effort to do so and Plaintiffs agree that on a motion to dismiss, it is inappropriate to do so.[23]

[23] *See* Section III (discussing that is premature to make a finding on a choice of law on a motion to dismiss); *see also ADP, LLC v. Bakshi*, Civ. Act. No. 15-8385, 2016 WL 1223557, at *6 (D.N.J.

**b. The manufacturing defect (Count 1) is plausibly pled under the NJPLA**

Under New Jersey law, a manufacturing defect is a deviation "from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae." *Myrlak v. Port Authority of N.Y. and N.J.*, 157 N.J. 84, 96 (1999) (quoting N.J.S.A. 2A:58C–2a). It occurs when the "product comes off the production line in a substandard condition based on the manufacturer's own standards or identical units that were made in accordance with the manufacturing specifications." As discussed, *see* Section V.A.2.a, Plaintiffs have so alleged. Compl. ¶¶ 46-47.

Importantly, "[t]he Supreme Court of New Jersey has held that the plaintiff may show the [manufacturing] defect through expert testimony or circumstantial evidence." *Ebenhoech v. Koppers Indus., Inc.*, 239 F. Supp. 2d 455, 472 (D.N.J. 2002) (citing *Myrlak*, 157 N.J. at 97). In such a scenario, "proof of proper use, handling, or operation of the product and the nature of the malfunction, may be enough to satisfy the requirement that something was wrong with it. Further, a defective condition can also be proven by the testimony of an expert." *Ebenhoech v. Koppers Indus., Inc*., 239 F. Supp. 2d 455, 472 (D.N.J. 2002). But Defendants' handling and packaging of Invokana is necessarily only in the knowledge of the defendants that discovery will reveal. Thus it is appropriate to withhold dismissal of this claim under New Jersey law given the broad scope of a manufacturing defect claim's proof.[24]

---

Mar. 29, 2016) ("[D]isputes require discovery and further exploration before a proper choice of law analysis can be performed.").

[24] Moreover, Defendants restate their confused plausibility versus particularity-level desired pleading standard under New Jersey law, just as they did under Tennessee law. Thus, for the same reasons as stated above, Plaintiffs need not prove their case in their complaint and answer propriety information necessarily only in Defendants' hands about "how" a drug was manufactured at this stage of the litigation. All they must do is allege facts that make it plausible that it is the case. They have done so for the same reasons stated in Section V.A.2.a., *supra*.

**c. The design defect (Count 2) is plausibly pled under the NJPLA**

Defendants insist that plaintiffs must show a reasonable alternative design and facts" to support that a reasonable alternative design is feasible. Under New Jersey law,

> "[a] plaintiff must prove either that the product's risks outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm. Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that is both practical and feasible."

*Schraeder v. Demilec (USA) LLC*, No. 12-6074, 2013 WL 5770670, at *2 (D.N.J. Oct. 22, 2013) (citing *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 570–71 (N.J. 1998)).

These elements of proof at trial, however, are not required to be proven at the pleading stage. An alternative design need not be pled because "it is not required that the Plaintiffs always plead a reasonable alternative design." *Id.* "A plaintiff must prove ***either*** that the product's risks outweighed its utility ***or*** that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." *Am. Cyanamid Co.*, 155 N.J. at 570–71 (emphasis in the original). Thus, it is almost always that "the jury [i]s required to perform a risk-utility analysis." *Lewis v. Am. Cyanamid Co*., 155 N.J. at 560. And a jury's evaluation of the risk-utility factors "may justify a conclusion that ***even though there is presently no alternative design*** which would make a product safer [liability may still be found]." *Smith v. Keller Ladder Co*., 275 N.J. Super. 280, 283-84 (N.J. App. Div. 1994) (emphasis added).

Even though not required under New Jersey law, as discussed, *see* Section V.A.2.b., *supra*, Plaintiffs have pointed to such a feasible alternative design: the existence of "alternative safer products" when compared against Invokana, which is "more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other

medications and similar drugs on the market to treat type 2 diabetes." Comp. ¶¶ 25, 51(b), (c).[25] But it is not only the existence of safer, alternative type 2 diabetes medications that form the basis for a design defect, it is also the insufficient and inadequately tested and labeled Invokana. Comp. ¶¶ 51(d), & (f). Defendants do not attempt to refute these allegations.

**d. The failure to warn claim (Count 3) is plausibly pled under the NJPLA**

As noted at Section V.A.2.c., *supra*, weighing the adequacy of Defendants' warnings is not appropriate on a motion to dismiss. This is equally as true under New Jersey law as Tennessee law. See *In re Ductile Iron Pipe Fittings ("DIPF") Direct Purchaser Antitrust Litig.*, No. 12-711, 2014 WL 3971620, at *6 (D.N.J. Aug. 13, 2014) ("In ruling on a motion to dismiss, the Court may not weigh evidence or otherwise decide which version of the facts is true.") (citing *Acevedo v. Monsignor Donovan High Sch.*, 420 F. Supp. 2d 337, 342 (D.N.J.2006)). Countless New Jersey Courts have held the same in the context of pharmaceutical cases. *See, e.g., In re Reglan Litig.*, No. A-2014-13T4, 2014 WL 5840281, at *7 (N.J. Super. Ct. App. Div. Nov. 12, 2014), leave to *appeal granted*, 224 N.J. 278 (App. Div. 2015); *Kendall v. Hoffman-La Roche, Inc.*, 209 N.J. 173, 197 (N.J. 2012). Thus, for the same reasons stated in Section V.A.2.c., *supra*, this Court should not dismiss Plaintiffs' failure to warn claim.

**e. Mrs. Robertson's express warranty claim (Count 4) is plausibly pled**

Defendants argue that plaintiffs failed to provide a pre-suit notice under New Jersey law of

[25] Again, Defendants restate their confused plausibility versus particularity-level desired pleading standard under New Jersey law, just as they did under Tennessee law. Thus, for the same reasons as stated above, Plaintiffs need not prove their case in their complaint and answer propriety information necessarily only in Defendants' hands about "how" a drug was designed at this stage of the litigation. All they must do is allege facts that make it plausible that it is the case. They have done so for the same reasons stated in Section V.A.2.b., *supra*.

her express warranty claim. But because it is premature to determine if Plaintiffs' express warranty claim should be analyzed under Tennessee or New Jersey law (and because Defendants have made no attempt, as is their burden, to argue which should apply) the question of pre-suit notice under New Jersey Law (if even applicable) is premature. *See* Section III.

Defendants' remaining quarrels with Plaintiffs' express warranty claim are the same as those outlined as to the Tennessee claim: they want "more." But for the same reasons that Plaintiffs' express warranty claim would survive under Tennessee law, it survives under New Jersey law. *See* Section V.A.2.d.1.

**4. Mrs. Robertson's Claim for Punitive Damages (Count 12) Survives**

Generally, New Jersey allows for punitive damages in cases where "the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's [FDA's] regulations, which information was material and relevant to the harm in question." N.J. Stat. Ann. § 2A:58C-5c. As Defendants point out, however, following *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but, importantly, before *Wyeth v. Levine*, 555 U.S. 555, the New Jersey appellate decision held that punitive damages could not be sought under the facts of *McDarby v. Merck & Co.*, 949 A.2d 223, 275–76 (N.J. Super. Ct. App. Div. 2008). *Wyeth* held that federal law does not preempt state torts claims imposing liability on drug labeling that the FDA had previously approved because FDA's "changes being effected" (CBE) regulation permits unilateral labeling changes that improve drug safety. 555 U.S. at 568 (citing 21 CFR §§ 314.70(c)(6)(iii)(A), (C)). As such, the Supreme Court stated, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." 555 U.S. 555, 570–71. Thus, subsequent to *Wyeth*, this District and other districts across the nation have called *McDarby's* reasoning into question. "The vitality of *McDarby* was subsequently cast into some doubt by the Supreme Court's decision in *Wyeth.*" *Sullivan v.*

*Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 534 n.8 (D.N.J. 2009). "The holding of *McDarby*, however, has been called into doubt by *Wyeth* … and *Forman v. Novartis Pharmaceuticals Corp*., 793 F. Supp. 2d 598 (E.D.N.Y. 2011)." *Hill v. Novartis Pharm. Corp.*, No. 1:06-cv-00939, 2012 WL 967577, at *2 (E.D. Cal. Mar. 20, 2012) (same).

Timing is critical. Because *McDarby* preceded *Wyeth*, the *McDarby* court did not have the ability to consider the Supreme Court's determination that a drug manufacturer may change the label of brand-name drugs without prior FDA approval for reasons of safety. Thus, it is possible for a drug manufacturer to come to know of information that would call for an updated warning (*i.e.*, knowingly withhold information from the FDA), but fail to update the labeling, thereby satisfying N.J. Stat. Ann. § 2A:58C-5c.

With respect to Tennessee, punitive damages are available for egregious conduct by Defendants. *See Hodges v. S.C. Toof & Co.*, 833 S.W.2d 896, 901 (Tenn. 1992); Tenn. Code Ann. § 29-39-104(a)(1). Plaintiffs have put Defendants on notice of their conduct and as such their claim for punitive damages is sufficiently pled.

### B. Mrs. Robertson's Design Defect-Based Claims Are Not Preempted By Federal Law

Invokana is a brand-name prescription drug for which there is currently no generic equivalent. Generally speaking, brand-name prescription drugs are regulated differently than generic prescription drugs. This is because it is the brand-name manufacturer that seeks approval from the FDA to market the drug and which is in possession of clinical testing data and safety information, conducted and collected both before and after a drug comes to market. By contrast, generic manufacturers do not generally conduct safety testing. Rather they are merely copying an existing formulation for a brand name drug. Indeed, that is why generic manufacturers must conform their product labels with those of the brand name manufacturers. 57 Fed. Reg. 17961

(1992) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval"). Courts have recognized this distinction and have generally ruled that state claims for failure to warn (and in some cases, design defect) against *generic* manufacturers are preempted. *See, e.g., In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, No. 2:11-MD-2226, 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012), *aff'd sub nom. In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014) (dismissing all generic propoxyphene cases in a MDL). Courts, however, have not typically extended this protection to brand name prescription drug manufacturers.

Despite the Supreme Court precedent recognizing this distinction, Defendants argue that their *brand*-name drug should still be protected from liability under a theory of *conflict* preemption theory because it is the FDA, not the Defendants, that approved its drug design, composition, and dosage. Def. Mot. at 21-27. While that may be true, it is the Defendants that submitted their drug for approval in the first instance. It is the Defendants that initially designed and developed Invokana, and submitted proposed labeling for the drug. Therein lies Defendants liability. Further, absent discovery regarding the regulatory submissions made by Defendants, as well as any communications between Defendants and the FDA, it is not what information was provided to the FDA regarding the safety of the drug. Thus, as a practical matter, any consideration of conflict preemption would be premature.

Nevertheless, Defendants cite to three Supreme Court cases that they claim require dismissal with prejudice. None of the three Supreme Court cases Defendants cite, as discussed below, at issue are on point, and certainly none of them mandate dismissal of Plaintiffs' claims.

First, *Wyeth* held that a brand-name drug manufacturer can be held liable for failure to warn claims because regulations allow a manufacturer to implement label changes with the

FDA's prior approval. Thus, the Court stated:

> Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case. . . . We conclude that it is not impossible for Wyeth to comply with its state-and federal-law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA.

*Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

The second case cited by Defendants, the *Mensing* case, reiterates *Wyeth* but instead does preempt failure-to-warn claims when a ***generic***, and not brand-name, drug is at issue.

> We recognize that from the perspective of [plaintiffs] Mensing and Demahy, finding pre-emption here but not in *Wyeth* makes little sense. Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, Wyeth would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, *substituted generic metoclopramide* instead, federal law pre-empts these lawsuits.

*PLIVA, Inc. v. Mensing*, 564 U.S. 604, 625 (2011) (emphasis added). The Plaintiff in this case took brand name Invokana, not a generic substitute—because no such generic drug exists. Compl. ¶ 8.

Finally, the third case cited by the Defendants, *Bartlett*, simply extended *Mensing* such that claims involving ***generic*** drugs applies to design-defect claims (and not only failure to warn claims as were at issue in *Mensing*). "As *PLIVA* made clear, federal law prevents *generic drug manufacturers* from changing their labels." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013) (emphasis added). Thus, these cases provide no basis for dismissal of a brand-name drug.

The Defendants cite several lower court decisions in jurisdictions not binding on this Court that extend the *Mensing* and *Bartlett* opinions beyond the realm of generic drugs – but

mostly applying preemption *outside the context of pharmaceutical drugs*. Def. Mot. at 24-25.

For example, Defendants cite to the Third Circuit case *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680 (3d Cir. Apr. 19, 2016). That citation is odd for multiple reasons. First, *Sikkelee* held that the Federal Aviation Act of 1994 (hardly a pharmaceutical case) does *not* act to preempt state-law based aircraft product liability claims. *Id.* at *1. The Third Circuit so held because of the "presumption against preemption [under which] Congress must express its clear and manifest intent to preempt an entire field of state law." *Id.* at *2. Second, the Third Circuit expressly states the opposite of the proposition for which Defendants say it stands for.

> In a series of recent preemption cases, the [Supreme] Court has **distinguished between brand-name drugs and their generic equivalents**, determining that at least some state law tort claims may be brought against brand-name drug companies because such companies have the ability to make some unilateral changes to their labels without additional regulatory preapproval, but such claims against generic drug manufacturers cannot survive a conflict preemption analysis because the generic manufacturers are bound by federal law to directly mimic their brand-name counterparts.

*Id.* at *55 (emphasis added).

As the Third Circuit boiled down so well, generic drug claims of all types usually fail, but branded-name drugs (like Invokana) are not preempted. Two sister courts in this Circuit agree, of course. "The Supreme Court has not addressed whether federal law can preempt state law design defect claims brought against manufacturers of brand-name or non-prescription drugs. I conclude that its preemption cases do not extend to the manufacturers of these products." *Brown v. Johnson & Johnson*, 64 F. Supp. 3d 717, 721 (E.D. Pa. 2014).

> [T]he same federal regulations that apply to generic manufacturers do not necessarily apply to brand-name manufacturers, such as the defendants. … This explains why the failure-to-warn claim brought against a generic drug manufacturer in PLIVA was preempted but failure-to-warn claim brought against the brand-name manufacturer in *Wyeth v. Levine* was not. … Following from this logic, I find that

> *Bartlett*—a case involving a generic manufacturer and following *PLIVA v. Messing*—does not apply to the plaintiff's design defect claim against a brand-name manufacturer. Under the dictates of *Wyeth v. Levine*, preemption is not warranted.

*Terry v. McNeil-PPC, Inc.*, No. 2:13-md-02436, 2015 WL 7075949, at *21-22 (E.D. Pa. Nov. 13, 2015).

The outlier cases cited by Defendants cannot be reconciled with the explicit language in *Mensing* and *Bartlett* and should be disregarded by the Court. As one district court noted about the rationale espoused by Defendants by the outside-of-this-circuit cases they cite, "[i]f this is the correct interpretation of *Bartlett*, then it appears virtually all design defect cases against generic and brand-name prescription drug manufacturers alike would be preempted." *Trahan v. Sandoz, Inc.*, No. 3:13-cv-350, 2015 WL 2365502, at *6 (M.D. Fla. Mar. 26, 2015). Defendants' interpretation of the law of federal preemption cannot be (and is not) correct.

**C. All of Mrs. Robertson's Claims against Johnson & Johnson Remain Valid**

As noted above, *see Section* V.A.1., *supra*, Johnson & Johnson had direct involvement in the development, sale, and marketing of Invokana. Even if this Court is not inclined to judicially notice the multitude of types and sources of materials supporting J&J's awareness of and participation in the development and marketing of Invokana, this Court should *still* allow claims against J&J to proceed at this stage in the litigation.

Plaintiffs' claims allege that J&J, *inter alia*, marketed *Invokana.* Compl ¶ *10.* Based on far less, indeed mere knowledge of a subsidiary's wrongdoing, the Northern District of Texas allowed such claims to proceed against J&J with respect to its medical device wholly-owned subsidiary, DePuy. *Lay v. DePuy Orthopaedics, Inc.* (*In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*), 2014 WL 3557392 (N.D. Tex. July 18, 2014). There, the court reasoned that Restatement (Second) of Torts §876(b) applies because J&J "is subject to liability

for harm to a third person resulting from the tortious conduct of another if [it] knows that the other's [here, Janssen's] conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself." *Id.* at *13. The case had already survived on a motion to dismiss on this ground and discovery revealed that the "evidence ... raises fact issues that the Johnson & Johnson Companies knew that DePuy was engaged in the manufacture and marketing of a defective product and that they provided assistance to DePuy in marketing that product." *Id.* That knowledge included, among other things, that its subsidiary was facing manufacturing problems with its hip components, which J&J continued to exercise control over marketing and advertising, that the J&J name was placed on packaging of the device, and that the J&J name was used in doctor marketing efforts. *Id.* at *13-15.

Both New Jersey and Tennessee recognize the Restatement (Second) of Torts §876(b). "The Supreme Court of New Jersey adopted the Restatement (Second) of Torts § 876(b) standard." *Shah v. Wisconsin*, No. 11-0419, 2011 WL 5192127, at *5 (D.N.J. Oct. 28, 2011) (citing *Tarr v. Ciasulli*, 181 N.J. 70, 853 A.2d 921, 928 (N.J. 2004)); *see also Failla v. City of Passaic*, 146 F.3d 149, 158 (3d Cir. 1998); *Hurley v. Atlantic City Police Dep't*, 174 F.3d 95, 129 (3d Cir. 1999); *Bondi v. Citigroup, Inc.*, No. L-10902-04, 2005 WL 975856, at *17 (N.J. Super Ct. Law Div. Feb. 28, 2005) (stating that courts in this circuit and in New Jersey recognize "civil aiding and abetting liability" as described in the Restatement (Second) of Torts § 876(b)). Tennessee has similarly adopted § 876(b). *See Caboodles Cosmetics, LP v. Caboodles, LLC*, 412 F. Supp. 2d 872, 880-81 (W.D. Tenn. 2006).

The facts alleged and/or judicially noticeable here support a claim under the Restatement (Second) of Torts §876(b). As noted above, this Court can take judicial notice of the fact that J&J: (1) directed the physical labeling of Invokana; (2) published media information about Invokana's method of action; (3) announced to its shareholders its hopes for an approval of Invokana in 2012;

(4) shared executives between J&J and Janssen; and (5) J&J's consumer brand director was (and remains) in charge of Invokana's marketing. Any one of these facts could lead a reasonable juror to believe that J&J's conduct constitutes a breach of duty and gives substantial assistance or encouragement to Janssen's conduct.

Moreover, Plaintiffs' design defect does not call for the Defendant's to reformulate Invokana *now*, it is a claim that they should not have submitted the formulation (*i.e.*, its design) in the first instance for approval. In other words, it is incumbent upon the drug manufacturer to make sure the drug is safe at all times – including the time the drug is first brought to market.

**D. Mr. Robertson's Loss-Of-Consortium Claim (Count 13) Survives**

Because Mrs. Robertson's claims survive, Mr. Robertson's derivative claims survive.

## VI. CONCLUSION

Plaintiffs' complaint meets the applicable pleading standards. As a result, Defendants' motion to dismiss should be denied in its entirety.

Respectfully submitted,

**SEEGER WEISS LLP**

By: /s/ Christopher A. Seeger
Christopher A. Seeger
Jeffrey Grand (*pro hac vice* pending)
Daniel R. Leathers
550 Broad Street Suite 920
Newark, New Jersey 07102
Telephone: (973) 639-9100
Facsimile: (973) 639-9393
E-mail: cseeger@seegerweiss.com
E-mail: jgrand@seegerweiss.com
E-mail: dleathers@seegerweiss.com

***Attorneys for Plaintiffs***

**CERTIFICATE OF SERVICE**

It is hereby certified that a true copy of the foregoing was served electronically via the Court's electronic filing system on the 15th day of August 2016, upon all counsel of record.

Dated: August 15, 2016

/s/ Christopher A. Seeger
Christopher A. Seeger